

DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS

21 FEB 2017

MEMORANDUM FOR SGVU

ATTN: JOSHUA CALCOTE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- Your paper, entitled "In the Name of Humanity" The 59th Medical Wing Clinical Investigation Program presented at/published to A Periodical Article for Publications in the AF Surgeon General's Newsletter in accordance with MDWI 41-108, has been approved and assigned local file #17098.
- 2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
- 3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
- 4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC Director, Clinical Investigations & Research Support

Linda Steel-Goodwin

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

- 1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D;
 Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP); Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
- 2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
- 3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
- 4. Attach a copy of your abstract, paper, poster and other supporting documentation.
- 5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
- 6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
- 7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
- 8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
- Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. Note: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
- 10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.
- 11. The Joint Ethics Regulation (JER) DoD 5500.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
 - "The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"
- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
 - "The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."
- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401 IP:
 - "The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS							
1. TO: CLINICAL RESEARCH 2. FROM: (Auth	nor's Name, Rank, Grade,	Office Symbol)	3. GME/GHSE ST	TUDENT:	4. PROTOCOL NUMBER:		
Calcote, Joshu	a - Contractor, 59 MD	W/SGVU	☐ YES 🏻		N/A		
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)							
N/A							
6. TITLE OF MATERIAL TO BE PUBLISHED OF	R PRESENTED:						
"In the Name of Humanity" - The 59th Medical Wing Clinical Investigation Program							
7. FUNDING RECEIVED FOR THIS STUDY? YES NO FUNDING SOURCE:							
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: YES NO							
9. IS THIS MATERIAL CLASSIFIED? YES	NO						
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? YES NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.							
11. MATERIAL IS FOR: DOMESTIC RELE	ASE FOREIGN REL	EASE					
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED. 11a. PUBLICATION/JOURNAL (List intended publication/journal.)							
11b. PUBLISHED ABSTRACT (List intended journal.)							
11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)							
11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)							
11e. OTHER (Describe: name of meeting, city, state, and date of meeting.) A Periodical Article for Publication in the AF Surgeon General's Newsletter							
12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?							
☐ YES ☑ NO ASSIGNED FILE # DATE							
13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).							
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I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.							
18. AUTHOR'S PRINTED NAME, RANK, GRADE Dr. Joshua C. Calcote, Contractor		19. AUTHOR'S SIGNA	19. AUTHOR'S SIGNATURE 20. DATE February 13, 201		20. DATE February 13, 2017		
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26. DATE REVIEWED		27. DATE FORWARDED TO 502 ISG/JAC			
February 17, 2017					
28. AUTHOR CONTACTED FOR RECOMMENDED O	R NECESSARY CHANGE	ES: NO YES If yes, give date.	N/A		
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"IN THE NAME OF HUMANITY" THE 59TH MEDICAL WING CLINICAL INVESTIGATION PROGRAM



The 59th Medical Wing (59 MDW) Clinical Research Division (CRD) is a 60-person organization that executes the largest Air Force Clinical Investigation Program (CIP) which aims to improve the quality of healthcare for DoD beneficiaries by generating an atmosphere of scientific inquiry, promoting an academic environment of high professional standing, and providing a means to assist in the accreditation of graduate medical education and other allied health training programs. The CRD CIP supports approximately 1,200 residents and fellows of the medical, dental, nursing, and biomedical science corps across 45 local training programs in the San Antonio, Texas area.

Functions of the CRD CIP include: regulatory oversight of research (~335 active studies); research subject protection; laboratory support for clinical investigations; maintenance and administration of surgical and procedural training protocols; and offering guidance and a funding stream for student scholarly activities.

THE HIGHEST STANDARDS

The CRD helped establish the 59 MDW Human Research Protection Program (HRPP) and is supporting the 59 MDW effort to become the <u>first</u> DoD facility that is nationally-accredited through the Association for the Accreditation of Human Research Protection Programs (AAHRPP) — the premier accrediting body for human subjects protection programs. The HRPP was realigned to enhance the comprehensiveness and quality of human subjects protection at the 59 MDW and to directly increase the knowledgebase, diligence, and efficiency of 59 MDW Institutional Review Board (IRB) members

and supporting staff. The IRB currently achieves a 25-day turn-around time for reviewing and approving non-exempt human research – 156% quicker than the national average for other elite AAHRPP-accredited organizations.

The CRD was granted full, continued Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) "Emeritus" status, marking 21 years of full accreditation. The animal research program and the CRD vivarium, housing five animal species, have earned numerous accolades and commendations and have developed best practices in animal care and use, records maintenance, and continuing education.

SPOTLIGHT ON RESEARCH

The Non-Human Research Subject Blood Donor Initiative, designed by the CRD, was presented by Erica Dean, BSN, BS, RN at the 2016 American Association for Laboratory Animal Science (AALAS) and the 2016 Military Health System Research Symposium (MHSRS) National Meetings and chosen for the AFSO21 brief during the 2016 Unit Effectiveness Inspection.



This Initiative resulted in a significant reduction in the number of animals required to support trauma-related protocols. Use of this CRD-produced protocol could drastically reduce the number of animals required to support trauma-and resuscitation-focused research resulting in greater community acceptance and additional research opportunities for other Clinical Investigation Facilities.

Col Paul Sherman, MD, in his study entitled, Brain Magnetic Resonance Imaging (MRI) and Neuropathological Effects of Hypobaric Exposure to 30,000 ft. and Hyperoxemic Exposure at Sea Level, wanted to investigate white matter injury seen with hypobaric (low pressure) exposure in our high altitude U-2 and F/A-18 pilots and aerospace physiology altitude chamber inside-observers.



To accomplish this, his team will expose miniature swine to varying levels of altitude and oxygen within a mock cockpit cage model where the swine will be free to move around, eat, and sleep. Publication of results is forthcoming.